DEC 2 9 2003 & TRADEMARY

PTO/SB/08A (10-01)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Offica: U.S. DEPARTMENT OF COMMERCE red to respond to a collection of information unless it contains a valid OMB Under the Paperwork Reduction Act of 1995, no persons are re-control number.

Substitute for form 1449A/PTO	Compl t if Known		
	Application Number 10/6	64,803	
INFORMATION DISCLOSURE	Filing Date Sep	tember 19, 2003	
STATEMENT BY APPLICANT	First Named Inventor Unc	halee Kositprapa	
	Art Unit		
(use as many sheets as necessary)	Examiner Name		
Sheet 1 of 5	Attorney Docket Number 141	-424	

			U.S. PAT	ENT DOCUMENTS	
Examiner Initials		Document Number Number - Kind Code ² (# known	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AA	us-3,174,901	03-23-1965	Sterne	
	AB	us-3,960,949	06-01-1976	Ahrens et al.	
	AC	us-4,166,800	09-04-1979	Fong	
	AD		06-21-1983	Tice et al.	
		us-4,687,777	08-18-1987	Meguro et al. Colombo et al.	
	AF	us- 4,839,177	06-13-1989	Cofombo et al.	
	AG	us- 4,891,223	01-02-1990 11-06-1990	Ambegaonkar et al.	
	AH			Zentner et al.	
	ΑI	us- 5,294,770	03-15-1994	Riddle et al.	
	AJ	us- 5,356,913	10-18-1994	Colca	
	AK		12-27-1994	Roy	
	AL	us-5,478,852	12-26-1995	Olefsky et al.	
	AM.		02-11-1997	Antonucci et al.	
	AN		08-19-1997	Geerke	
		∪s-5,681,584	10-28-1997	Savastano et al.	
	AP	us- 5,698,220	12-16-1997	Cardinal et al.	
	AO.	us-5,719,188	02-17-1998	Colca	
	AR	us- 5,859,037	01-12-1999	Whitcomb	
	AS	us- 5,916,584	06-29-1999	O'Donoghue et al.	
	AT	us- 5.952.356	09-14-1999	Tkeda et al.	

	FOREIGN PATENT DOCUMENTS								
Examiner Initials		Foreign Patent Document Course Code 3 - Number 4 - Kind Code 5 (# known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Peges, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶			
	_								
	_								
	_								
	_								
	_								

Examiner Signature	Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Drew line through citation if not in

"EXAMINE: Initial if informace considering, whether or not clatative is in conformance with MPEP 009. Unw line through client in in or in conformance and or considered, include copy of this form with next communication to applicant.

1 Applicant's unique clatation designation number (optional). 3 See Kinds Codes of USEPT Posterill Documents at www.usclop.cog or MPEP
90.10.4. 2 Eiter (100% that is asseed the objective of the option of the option of course, by the horistic roods (WPPO Standard ST.3). 4 For Jepanese patent documents, by the indication of the year of the region of the disposance must precede the serial number of the posterior document. 3 Kind of document by the appropriate symbols as indicated on the document with WPPO Standard ST.1 of 16 pressibs. 3 Applicant is to piose a check mark the of the posterior of the document under WPPO Standard ST.1 of 16 pressibs. 3 Applicant is to piose a check mark the of the posterior of the pos English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Tree will very depending upon the needs of the individual case. Any comments on the annount of time you are required to complete this from shade the sent to the Chief Information Officer, U.S. Patient and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner For Patients, Washington, DC 20231.



PT0/58/09A (10-01)
Approved for use through 1031/2002.0 MB 0551-0351
OR RESUltation Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB. Under the Paper control number.

Substitute for form 1449A/PTO	C mplet if Known		
INFORMATION DISCUSOR COURSE	Application Number	10/664,803	
INFORMATION DISCLOSURE	Filing Date	September 19, 2003	
STATEMENT BY APPLICANT	First Named Inventor	Unchalee Kositprapa	
	Art Unit		
(use as many sheets as necessary)	Examiner Name		
Sheet 2 of 5	Attorney Docket Number	141-424	

			U.S. PAT	ENT DOCUMENTS	
Examiner Initials	No.1	Document Number Number - Kind Code ² (if known		Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Us- 5,955,106	09-21-1999 01 - 04-2000	Moeckel et al.	
	AV AW	us-6,011,049 us-6,031,004	02-29-2000	Timmins et al.	
	AX	us-6,099,859	08-08-2000	Cheng et al.	
	AY AZ	Us-6,153,632 Us- 6,191,162	11-28-2000 02-20-2001	Rieveley Byrd et al.	
	BA	us. 6,248,363	06-19-2001	Patel et al.	-
	BB	us- 6,291,495	09-18-2001	Rieveley	
		us- 6,296,874 us- 6,329,403	10-02-2001	Cutie et al. Odaka et al.	
		US- 6,383,471	05-07-2002	Chen et al.	
		∪s-6,403,121	06-11-2002	Adjei et al.	
	BG.	US- 2002/0071866 US-6,451,342	06-13-2002 09-17-2002	Geerke Adjei et al.	
	밝	us-6,475,521	11-05-2002	Timmins et al.	
	BJ	us- 6,524,621	02-25-2003	Adjei et al.	
	BK. BL		06-19-2003 06-26-2003	Dhawan et al.	
	BM	us- 2003/0118649	06-26-2003	Gao et al.	
	BN	us- 6,599,284	07-29-2003	Faour	

	FOREIGN PATENT DOCUMENTS							
Examiner initials		Foreign Patent Document County Code 3 - Number 4 - Kind Code 5 (# known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	те		
	CA	WO 96/09823 '	04-04-1996	Luo et al.				
	CB	WO 98/11879 '	03-26-1998	Shell et al.				
		WO 98/55107 ~	12-10-1998	Shell et al.				
	CD	WO 99/47128 /		Timmins et al.				
	CE_	WO 99/55320		Nishii et al.				
	CF_	WO 00/28989	05-25-2000	Lewis et al.				
	CG_	WO 00/72827 +	12-07-2000	Straub et al.				
	CH	WO 01/35940	05-25-2001	Lewis et al.				
	CI	WO 01/35941	05-25-2001	Lilliot et al.				
	CJ	WO 01/82875	11-08-2001	Cutie et al.				

Examiner Signature		Date Considered	
*EXAMINER:	initial if reference considered, whether or not citation is in conformant	e with MPEP 609	Draw line through citation if not in

*EXCIMITE: Initial interface consistency, which or not detailed in in conformation with MPLP 900. Draw this through citation in not in *Application surject calcidation designation consistency continues (e.g., page 100 to 4. *Enter Office that issued the document, by the two-letter code (MPPC blandard 61.3). *For Japanese palart documents, the page propriets symbols as inclinated on this document of the MPMC blandard 61.3). *For Japanese palart documents, the page propriets symbols as inclinated on the document of the MPMC blandard 51.3 *For Japanese and a check make their of the document of the MPMC blandard 51.3 *For Japanese and calcidation of the document of the MPMC blandard 51.3 *For Japanese and calcidation of the document of the MPMC blandard 51.3 *For Japanese and calcidation of the document of the MPMC blandard 51.4 *For Japanese and calcidation of the document of the MPMC blandard 51.4 *For Japanese and calcidation of the document of the MPMC blandard 51.4 *For Japanese and calcidation of the MPMC blandard 51.4 *For Japanese and calcidation of the MPMC blandard 51.4 *For Japanese and calcidation of the MPMC blandard 51.4 *For Japanese and Calcidation of the MPMC blandard 51.4 *For Japanese and Calcidation of the MPMC blandard 51.4 *For Japanese and Calcidation of the MPMC blandard 51.4 *For Japanese and Calcidation of the MPMC blandard 51.4 *For Japanese and Calcidation of the MPMC blandard 51.4 *For Japanese and Calcidation of the MPMC blandard 51.4 *For Japanese and Calcidation of the MPMC blandard 51.4 *For Japanese and Calcidation of the MPMC blandard 51.4 *For Japanese and Calcidation of the MPMC blandard 51.4 *For Japanese and Calcidation of the MPMC blandard 51.4 *For Japanese and Calcidation of the MPMC blandard 51.4 *For Japanese and Calcidation of the MPMC blandard 51.4 *For Japanese and Calcidation of the MPMC blandard 51.4 *For Japanese and Calcidation of the MPMC blandard 51.4 *For Japanese and Calcidation of the MPMC blandard 51.4 *For Japanese and Calcidation of the MPMC blandard 51.4 * English language Translation is attached.

Burden Hyer Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual cases. Any commentate on the ancest of their separate representations of the complete the stem should be sent to the Chief information Officer, U.S. Patient and Trademark Office, Washington, DC 20231, DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patients, Washington, DC 20231.



PTO/SB/08A (10-01)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent end Trademerk Office: U.S. DEPARTMENT OF COMMERCE
red to respond to a collection of information unless it contains a valid OMB Under the Paperwork Reduction Act of 1995, no pe

Substitute for form 1449A/PTO		omplet if Known
INCODER TION DIGOLOGUES	Application Number	10/664,803
INFORMATION DISCLOSURE	Filing Date	September 19, 2003
STATEMENT BY APPLICANT	First Named Inventor	Unchalee Kositprapa
	Art Unit	
(use as many sheets as necessary)	Examiner Name	
Sheet 3 of 5	Attorney Docket Number	141-424

	U.S. PATENT DOCUMENTS						
Examiner	Cito	Document Number	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where		
Initials		Number - Kind Code ² (if known		Applicant of Cited Document	Relevant Passages or Relevant Figures Appear		
		US-					
		US-					
		US-					
		US-					
		US-					
		US-					
		US-					
		US-					
		US-					
		US-					
		US-					
		US-					
		US-					
		US-					
		US-					
		US-					
		US-					
		US-					
		US-					
	-	US-					

		FOR	EIGN PATENT D	OCUMENTS		
Examiner Initials		Foreign Patent Document County Code3 -Number ⁴ - Kind Code ⁵ (* Anount)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevent Passages or Relavant Figures Appear	١,
		WO 02/28181	04-11-2002	Gidwani et al.		Т
		WO 03/004009		Matharu et al.		Γ
		WO 03/035029	05-01-2003	Louie-Helm et al.		L
	CN	WO 03/047529	06-12-2003	Seth et al.		Г
	CO	EP 0 169 105	01-22-1986	Zentner et al.		L
	CP.	EP 0 283 369	09-21-1988	Wiernsperger et al.		
	co.	EP 0 381 181	08-08-1995	Wenzel et al.		
	CR	EP 0 749 751	12-27-1996	Ikeda et al.		L
	CS	EP 0 753 298	11-21-2001	Tsujita et al.		L
	CT	ED 0 781 120	107-02-2003	Moeckel et al.		

CM WO 03/035029		Louie-Helm et al.	
CN WO 03/047529		Seth et al.	
CO EP 0 169 105		Zentner et al.	
CP EP 0 283 369	09-21-1988	Wiernsperger et al.	
CO EP 0 381 181		Wenzel et al.	
CR EP 0 749 751	12-27-1996	Ikeda et al.	
CS EP 0 753 298		Tsujita et al.	
CT EP 0 781 129	07-02-2003	Moeckel et al.	
Examiner		Date	
Signature		Considered	

Cognision | London |



PTO/SB/08B (10-01)
Approved for use through 10/31/2002 OMB 0651-0301
Itent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
spond to a collection of information unless it contains a valid OMB

Substitute for form 1449B/PTO
INFORMATION DISCLOSURE

Compl t if Known
Application Number | 10/664,803
Filling Date | September 19, 2003
First Named Inventor | Unchalee Kositprapa
Group Art Unit | Examiner Name | Attorney Docket Number | 141,424

STATEMENT BY APPLICANT
(use as many sheets as necessary)
Sheet | 4 | of | 5

Examiner

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the Evernine Cito itam (book, magazine, journal, sarial, symposium, catalog, etc.), date, page(s), volume-issue No.1 DA P. Karttunen et al., International Journal of Clinical Pharmacology, Therapy and Toxicology, "The pharmacokinetics of metformin: a comparison of the properties of a rapid release and a sustained-release preparation" Vol. 21, No. 1 -1983, pp. 31-36. P.J. Pentikainen, International Journal of Clinical Pharmacology, Therapy and DB Toxicology, "Bioavailability of metformin. Comparison of solution, rapidly dissolving-tablet, and three sustained-release products", Vol. 24, No. 4 - 1986, pp. 213-220. DC Finnish Monograph of the Diformin®, Retard tablet, with English translation DD O.J. Lucis, MD, Ph.D., MSC, Canada Medical Association J. Pharmacologic Update "The status of metformin in Canada" Vol. 128, January 1, 1983, pgs. 24-26. DE G. Belcher and D.R. Matthews Experiment and Clinical Endrocrinology & Diabetes, "Safety and tolerability of pioglitazone" Suppl. 2 (2000) pgs. 267-273. DF Daniel Einhorn, MD et al., Clinical Therapeutics "Pioglitazone Hydrochloride in Combination with Metformin in the Treatment of Type 2 Diabetes Mellitus: A Randomized, Placebo-Controlled Study", Vol. 22, No. 12, 2000 pgs. 1395-1413. DG National Institute for Clinical Excellence Technology Appraisal Guidance - No. 21. "Guidance on the Use of Pioglitazone for Type 2 Diabetes Mellitus" March 2001, pgs. 1-13. DH The Pharmaceutical Journal, Vol. 265, No. 7122, p. 710 November 11, 2000 Clinical (abstract only).

	Signature	Considered
Ε	XAMINER: Initial	if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance
п	nd not considered.	Include copy of this form with next communication to applicant.

Date

¹ Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

Burden Hoor Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this torm should be sent to the Inched Information Office, U.S. Petent and Tradement—Office, Wearhington, D.C. 2023. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Palents, Weshington, D.C. 2023.



PTO/SB/08B (10-01)
Approved for use through 10/31/2002. OMB 0651-0031
S. Palent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
to respond to a collection of Information unless it contains a valid OMB

Substitute for from 1449BPTO
INFORMATION DISCLOSURE
STATEMENT BY APPLICANT
(ase as meny sheets as necessary)
Sheet | S |
Sheet

		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
Exeminer Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the litem (book, magazine, journal, serial, symposium, calalog, etc.), date, page(s), volume-lesue number(s), unitable, ruly and/or country where unitablished.	T ²
	DI	Product Labeling for Glucophage® XR (July 2002).	
	DΊ	ADA Professional Section Member Supplement 047 and 0503-506 (Poster) p. A110; A117 June 1999.	
	DK	Website www.findarticles.com, Clinician Reviews, "Insulin-Sensitizing Diabetes Agent" September 1999.	
	DL	ACTOS® product label, Physician's Desk Reference, 55th Edition, pp. 3171-3175	
		Rote Liste No. 11081 the Medicament Mediabet of MEDICE, ChemPharm. Fabrik Pütter GmbH & Co. KG, Kuhloweg 37-39 Iserlohn/Germany, Editio	
		Cantor Verlag für Medizin und Naturwissenschaften GmbH, 1993.	
		·	
			L

Examiner Signature	/Aradhana Sasan/	Date Considered	06/21/2010

*EXAMINER: Initial # reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant to Date a check mark here if English language Translation is situated. Butden Floor Statement: This form is estimated to late 20 hours to complete. Time will vary deepending upon the most of the individual case. Any comments on the emount of time you are required to complete this form should be earl to the Chief Reformation Officer, U.S. Petent and Trademant and Chief Chief Peter (2017) (